UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

NYCOMED GmbH and WYETH, Plaintiffs, v. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. 1:08-00827 (RAG) Judge Ronald A. Guzman Magistrate Judge Nan R. Nolan **FILED ELECTRONICALLY**

ANSWER, DEFENSES, COUNTERCLAIMS AND JURY DEMAND OF DEFENDANTS APOTEX INC. AND APOTEX CORP.

Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") hereby answer the Complaint of Plaintiffs Nycomed GmbH and Wyeth—for which every allegation not expressly admitted is denied—as follows:

1. Nycomed GmbH is a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany.

ANSWER: Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 1, and therefore denies the same.

2. Wyeth is a Delaware corporation with offices at Five Giralda Farms, Madison, NJ 07940.

ANSWER: Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 2, and therefore denies the same.

3. Nycomed GmbH is at times referred to hereinafter as "Nycomed."

ANSWER: Admitted.

4. Upon information and belief, Defendant Apotex Inc. is a corporation incorporated and existing under the laws of Canada and having a principal place of business at 380 Elgin Mills Road East, Richmond Hill, Ontario, Canada L4C 5H.

ANSWER: Apotex admits that Apotex Inc. is a Canadian corporation. Apotex denies the remaining allegations of Paragraph 4.

5. Upon information and belief, Defendant Apotex Corp. is a Delaware corporation having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Admitted. Further answering, Apotex denies that Apotex Corp. is a proper party to this suit, and further denies that subject matter jurisdiction is proper for any claims asserted against Apotex Corp.

6. Upon information and belief, Apotex Corp. is the U.S. subsidiary of Apotex Inc.

ANSWER: Denied.

7. Apotex Inc. and Apotex Corp. are at times referred to hereinafter collectively as "Apotex."

ANSWER: Admitted.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c), 1391(d), and 1400(b).

ANSWER: Paragraph 8 states legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that this action purports to arise under the patent laws. Further answering, for purposes of this action only, Apotex does not contest venue. Further answering, Apotex denies that subject matter jurisdiction is proper for any claims asserted against Apotex Corp. Apotex denies the remaining allegations of Paragraph 8.

9. Apotex has designated William A. Rakoczy of Rakoczy Molino Mazzochi Siwik LLP, 6 West Hubbard Street, Suite 500, Chicago, Illinois 60610, as Apotex's

agent authorized to accept service of process for Apotex in this action, and has thereby consented to personal jurisdiction in this district.

ANSWER: Paragraph 9 states legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that, pursuant to U.S. Food and Drug Administration ("FDA") rules and regulations, Apotex Inc. identified its outside litigation counsel as Apotex Inc.'s agent for accepting service of process for an action against Apotex Inc. arising out of Apotex Inc.'s Abbreviated New Drug Application ("ANDA") for Pantoprazole Sodium Injectable, I.V. 40 mg. Further answering, for purposes of this action only, Apotex does not contest personal jurisdiction. Apotex denies the remaining allegations of Paragraph 9.

10. Upon information and belief, Apotex sells various products and does business throughout the United States including this district.

ANSWER: Denied.

BACKGROUND FOR CLAIM FOR RELIEF UNDER 35 U.S.C. § 271(e)(2)

11. Wyeth Pharmaceuticals Inc., a wholly-owned subsidiary of Wyeth, is the holder of New Drug Application ("NDA") No. 20-988, by which the United States Food & Drug Administration ("USFDA") granted approval for pantoprazole sodium injection 40mg, which is marketed and sold by the Plaintiffs in the United States under the trade name "PROTONIX® I.V."

ANSWER: Paragraph 11 states legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that the electronic version of FDA's publication, *Approved Drug Products with Therapeurtic Equivalence Evaluations* (commonly known as the "Orange Book"), identifies "WYETH PHARMS INC" as the applicant for New Drug Application No. 20-988 for PROTONIX® IV (Pantoprazole Sodium) Injectable 40 mg. Apotex denies the remaining allegations of Paragraph 11.

12. Nycomed is the owner of United States Patent No. 6,780,881 B2 ("the '881 patent"), which was duly and legally issued on August 24, 2004, and which discloses and claims certain pantoprazole preparations and injections. The sodium salt of pantoprazole is the active ingredient in PROTONIX® I.V.

ANSWER: Paragraph 12 states legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that, according to the records of the United States Patent and Trademark Office ("USPTO"), on or about August 24, 2004, the USPTO issued U.S. Patent No. 6,780,881 B2 (the "'881 patent"), entitled "FREEZE-DRIED PANTOPRAZOLE PREPARATION AND PANTOPRAZOLE INJECTION," to Rudolph Linder and Rango Dietrich; that the USPTO's electronic assignment database identifies "NYCOMED GMBH" as the assignee of the '881 patent; and that, according to FDA's electronic Orange Book and the FDA-approved labeling, PROTONIX® IV contains pantoprazole sodium. Apotex denies that the '881 patent was "duly and legally issued." Apotex denies the remaining allegations of Paragraph 12.

13. Wyeth is the exclusive licensee of the '881 patent in the United States.

ANSWER: Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 13, and therefore denies the same.

14. A copy of the '881 patent is attached as Exhibit A.

ANSWER: Apotex admits that what purports to be a copy of the '881 patent is attached to the Complaint as Exhibit A. Apotex denies the remaining allegations of Paragraph 14.

15. Upon information and belief, Apotex filed in the USFDA an Abbreviated New Drug Application ("ANDA"), including a certification with respect to the '881 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to manufacture, use or sell Pantoprazole Sodium Injectable, I.V. 40 mg, prior to expiration of the '881 patent.

ANSWER: Apotex admits that Apotex Inc. filed an ANDA for Pantoprazole Sodium Injectable, I.V. 40 mg; and that Apotex Inc.'s ANDA contains a so-called "paragraph IV certification" stating that the '881 patent is invalid, unenforceable and/or not infringed by Apotex

Inc.'s ANDA product. Apotex denies that Apotex Corp. filed or submitted any such ANDA. Apotex denies the remaining allegations of Paragraph 15.

16. Apotex's ANDA No. 79-197 lists pantoprazole sodium as the active ingredient in an injectable dosage form of the drug.

ANSWER: Apotex admits that Apotex Inc. filed an ANDA for Pantoprazole Sodium Injectable, I.V. 40 mg. Apotex denies the remaining allegations of Paragraph 16.

17. Upon information and belief, the Pantoprazole Sodium Injectable, I.V. 40 mg drug that is the subject of Apotex's ANDA will be manufactured by Apotex.

ANSWER: Apotex admits that Apotex Inc. filed an ANDA with FDA seeking approval to commercially manufacture, use and sell Pantoprazole Sodium Injectable, I.V. 40 mg. Apotex denies the remaining allegations of Paragraph 17.

18. By letter dated December 21, 2007, Apotex sent a notice to Nycomed and Wyeth in which Apotex represented that it had filed an ANDA for Pantoprazole Sodium Injectable, I.V. 40 mg, including the certification with respect to the '881 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

ANSWER: Apotex admits that, in a letter dated December 21, 2007, Apotex Inc. provided the requisite notice of Apotex Inc.'s ANDA and paragraph IV certification to Nycomed GmbH and Wyeth Pharmaceuticals Inc. Apotex denies the remaining allegations of Paragraph 18.

19. Nycomed received notice of the Apotex certification no earlier than December 24, 2007.

ANSWER: Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 19.

20. Wyeth received notice of the Apotex certification no earlier than January 2, 2008.

ANSWER: Apotex is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 20.

CLAIM FOR RELIEF UNDER 35 U.S.C. § 271(e)

21. Because Apotex seeks approval of its ANDA to engage in the commercial manufacture, use or sale of a drug claimed in the '881 patent before its expiration, Apotex has infringed the '881 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

22. Nycomed and Wyeth are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Apotex's ANDA be a date that is not earlier than the expiration date of the '881 patent, or any later expiration of exclusivity for the '881 patent to which Nycomed and/or Wyeth is or becomes entitled to.

ANSWER: Denied.

23. Upon information and belief, Apotex was aware of the existence of the '881 patent and was aware that the filing of its ANDA and certification with respect to the '881 patent constituted an act of infringement of that patent.

ANSWER: Denied.

24. Apotex's statement of the factual and legal bases for its opinion regarding non-infringement and invalidity of the '881 patent is devoid of an objective good faith basis in either the facts or the law.

ANSWER: Denied.

25. This case is an exceptional one, and Nycomed and Wyeth are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

ANSWER: Denied.

* * *

Apotex denies all allegations not expressly admitted herein. Apotex further denies that Plaintiffs are entitled to any of the relief requested in the Complaint (including Paragraph 26 thereof), and requests that Plaintiffs' complaint be dismissed with prejudice and that Apotex be awarded its fees and costs incurred defending this suit under 35 U.S.C. § 285.

SEPARATE DEFENSES

Without prejudice to the denials set forth in their Answer, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Apotex Inc. and Apotex Corp. assert the following defenses to the Complaint:

First Defense

The claims of U.S. Patent No. 6,780,881 B2 (the "'881 patent") are invalid for failure to satisfy one or more conditions for patentability under Title 35 of the United States Patent Code.

Second Defense

The manufacture, use, sale, offer for sale or importation of the Pantoprazole Sodium Injectable, I.V. 40 mg that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '881 patent.

Third Defense

Apotex Corp. is not a proper party to this action.

Fourth Defense

The Court lacks subject matter jurisdiction over any claims asserted against Apotex Corp.

Fifth Defense

The Complaint fails to state a claim upon which relief can be granted.

Sixth Defense

Any additional defenses or counterclaims that discovery may reveal, including, but not limited to, defenses of unenforceability.

COUNTERCLAIMS

Apotex Inc., for its Counterclaims against Nycomed GmbH and Wyeth (collectively, "Plaintiffs"), alleges as follows:

The Parties

1. Apotex Inc. is a corporation incorporated and existing under the laws of Canada with a place of business in Ontario, Canada.

2. Nycomed GmbH purports to be a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany.

3. Wyeth purports to be a Delaware corporation with offices at Five Giralda Farms, Madison, NJ 07940.

Jurisdiction and Venue

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have availed themselves of the rights and privileges of this forum by suing Apotex Inc. in this District, and because Plaintiffs conduct substantial business in, and have regular and systematic contacts with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Patent-In-Suit

8. On or about August 24, 2004, the United States Patent and Trademark Office issued U.S. Patent No. 6,780,881 B2 (the "'881 patent"), entitled "FREEZE-DRIED PANTOPRAZOLE PREPARATION AND PANTOPRAZOLE INJECTION," to Rudolph Linder and Rango Dietrich.

9. Plaintiffs purport and claim to own, and/or to have the right to enforce, the '881 patent.

10. On or about February 7, 2008, Plaintiffs filed this action against Apotex Inc. alleging infringement of the '881 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT I
(Declaration of Non-Infringement of the '881 Patent)

11. Apotex Inc. incorporates by reference the allegations of Paragraphs 1-10.

12. A present, genuine, and justiciable controversy exists between Plaintiffs and Apotex Inc. regarding, *inter alia*, non-infringement of the '881 patent.

13. The manufacture, use, sale, offer for sale or importation of the Pantoprazole Sodium Injectable, I.V. 40 mg that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '881 patent.

14. Apotex Inc. is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the Pantoprazole Sodium Injectable, I.V. 40 mg, that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '881 patent.

COUNT II
(Declaration of Invalidity of the '881 Patent)

15. Apotex incorporates by reference the allegations of Paragraphs 1-14.

16. A present, genuine, and justiciable controversy exists between Plaintiffs and Apotex Inc. regarding, *inter alia*, the invalidity of the claims of the '881 patent.

17. The claims of the '881 patent are invalid for failure to satisfy one or more conditions for patentability under Title 35 of the United States Patent Code.

18. Apotex Inc. is entitled to a declaration that the claims of the '881 patent are invalid.

REQUEST FOR RELIEF

WHEREFORE, Apotex Inc. respectfully requests that this Court enter Judgment in its favor and against Plaintiffs Nycomed GmbH and Wyeth as follows:

(a) Declaring that the manufacture, use, sale, offer for sale or importation of the Pantoprazole Sodium Injectable, I.V. 40 mg, that is the subject of Apotex's ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '881 patent;

(b) Declaring that the claims of the '881 patent are invalid;

(c) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Apotex Inc. its attorneys' fees, costs, and expenses in this action; and

(d) Awarding Apotex Inc. any further and additional relief as the Court deems just and proper.

JURY DEMAND

Apotex hereby demands a trial by jury on all issues so triable.

Dated: April 1, 2008.

Respectfully submitted,

APOTEX INC. and APOTEX CORP.

By: /s/ William A. Rakoczy

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CERTIFICATE OF SERVICE

I, William A. Rakoczy, an attorney, hereby certify that on this 1st day of April, 2008, a true and correct copy of the foregoing Answer, Defenses, Counterclaims and Jury Demand of Defendants Apotex Inc. and Apotex Corp. was filed by the Court's Electronic Case Filing (ECF) system and served as follows to counsel for Plaintiffs:

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